

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 1:20-cv-01744-CFC
)	
WALMART INC. AND WAL-MART)	
STORES EAST, LP,)	
)	
Defendants.)	
)	

JOINT STATUS REPORT

Pursuant to the Court's November 19, 2021, Order (D.I. 59), the parties hereby submit this Joint Status Report.

I. Post *Ruan* and *Kahn* Status Update

Following the United States Supreme Court's resolution of *Ruan v. United States* and *Kahn v. United States*, 2022 WL 2295024 (Jun. 27, 2022) (*Ruan*), the parties met and conferred on July 5, 2022. The parties disagree regarding appropriate next steps in light of the *Ruan* decision. Their respective positions are set forth below.

A. Walmart's Position

In light of *Ruan*, Walmart believes the United States should voluntarily dismiss its First and Second Claims for Relief. First, *Ruan* held that doctors are not liable under 21 U.S.C. § 841(a) unless they "knowingly" issue invalid

prescriptions, and the Court called that a “strong scienter requirement” that the United States could not evade or substitute for a negligence test. ___ S. Ct. ___, 2022 WL 2295024, at *1, *8 (2022). Section 1306.04(a) includes the same “knowingly” element for pharmacist liability, yet the Complaint repeatedly tries to bypass that scienter requirement in ways that *Ruan* confirmed are impermissible. Second, Justice Alito’s concurrence—in a portion the majority did not dispute—confirms that mere deviations from objective professional norms are not sufficient to fall outside Section 1306.06’s “usual course” test; instead the pharmacist must cease acting as one *at all*, such as by pursuing objectives “alien” to the profession. *Id.* at *15. Regardless of whether that standard is viewed as an objective test, a subjective test, or both, the Complaint does not come close to satisfying it, through “circumstantial evidence” or otherwise. *See id.* at *9.

The United States refused Walmart’s request to voluntarily dismiss its First and Second Claims for Relief. Walmart therefore suggested the parties request that the Court set a supplemental briefing schedule in light of *Ruan* with respect to Walmart’s pending Motion to Dismiss (D.I. 26). Walmart would file its supplemental brief by August 1, 2022. The United States would respond by August 22, 2022. And Walmart would file a reply by September 2, 2022.

With respect to the United States’ proposal below to file an Amended Complaint, Walmart maintains that the existing Complaint is legally deficient and

should be dismissed. Through the meet-and-confer process to prepare this Joint Status Report, the United States has not informed Walmart—after more than five years of investigation by the Justice Department—what new factual allegations or legal theories it intends to assert in an Amended Complaint in an effort to shore up these deficiencies following the *Ruan* decision. For that reason, Walmart submits it must review the United States’ draft Amended Complaint before taking a position about whether or not Walmart would oppose its filing. The United States proposes a schedule below for seeking leave to amend its Complaint. Walmart proposes the alternative following schedule if the Court permits the United States to seek leave to file an Amended Complaint:

1. Within 21 days of the Court’s entry of an order in response to this Joint Status Report, the United States will share a draft of its proposed Amended Complaint with Walmart;
2. Once the United States shares a draft of its proposed Amended Complaint, the parties shall have 14 days to meet and confer on whether Walmart will provide written consent to its filing under Fed. R. Civ. P. 15(a)(2);
3. Within five days of the conclusion of the parties’ meet and confer, if Walmart declines to provide written consent to the

amendment, the United States shall file a motion for leave to amend its Complaint.

B. The United States’ Position

The United States disagrees with Walmart’s interpretation of *Ruan* and its view of how that decision applies to the Complaint. The United States summarizes below its disagreement and its proposed next steps.

The majority in *Ruan*, while interpreting a criminal provision (21 U.S.C. § 841(a)) that is not at issue in this case, nevertheless clarified some principles relevant in this civil case in ways that support the United States’ position. It held that the core standards at issue in Sections 1306.04 and 1306.06—the “usual course of professional practice” and “legitimate medical purpose”—are “objective criteria.” 2022 WL 2295024, at *9. And it held that the government can prove a knowing departure from those objective criteria “through circumstantial evidence,” *id.*, just as the United States has explained it would do in this case. *See* D.I. 42 at 9-12.

Walmart suggests that Justice Alito’s concurrence defines the meaning of the “usual course” standard, but the *Ruan* majority did not adopt the very different, *subjective* standard proposed by Justice Alito—who concurred only in the judgment, not in the majority opinion. In particular, Justice Alito protested that “an objective understanding of the ‘in the course of professional practice’ standard

would suggest” a focus on whether the physician was “acting as a *good* physician,” and he explained that he instead would have adopted a subjective standard focused on whether a doctor “acts in subjective good faith” or is motivated by “[o]bjectives ... alien to medical practice.” 2022 WL 2295024, at *15 (emphasis in original). The *Ruan* majority, however, did not adopt the standard urged by Justice Alito but rather adhered to its view that the “usual course of professional practice” and “legitimate medical purpose” requirements establish “objective criteria.” *Id.* at *9.

Under the standard set forth by the *Ruan* majority, the Complaint’s dispensing-related claims are soundly stated. The Complaint alleges that Walmart knowingly filled controlled-substance prescriptions that did not meet Section 1306.04(a)’s objective criteria. And it alleges that Walmart pharmacists violated Section 1306.06’s objective “usual course of ... professional practice” standard because their conduct in filling controlled-substance prescriptions failed to comply with basic standards of the pharmacy profession.

In any event, the United States requests an opportunity to amend its Complaint for several purposes, including to add factual allegations that further demonstrate Walmart’s liability under Sections 1306.04 and 1306.06 consistent with the clarifications provided by the Supreme Court in *Ruan*. The United States submits that it would be more efficient for the parties to address the potential effect of *Ruan*, and for the Court to consider Walmart’s arguments in support of its

motion to dismiss, after the United States has had an opportunity to amend its complaint, if permitted to do so. The United States respectfully submits that the schedule Walmart proposes with respect to potential amendment of the Complaint is too compressed given the scope of the Complaint's allegations. The United States proposes that the Court enter an order as follows:

1. Within forty-five days of the Court's entry of the order, the United States will share a draft of its proposed Amended Complaint with Walmart;
2. Once the United States shares a draft of its proposed Amended Complaint, the parties shall have fourteen days to meet and confer on whether Walmart will provide written consent to its filing under Fed. R. Civ. P. 15(a)(2);
3. Within five days of the conclusion of the parties' meet and confer, if Walmart declines to provide written consent to the amendment, the United States shall file a motion for leave to amend its Complaint.

II. Other Issues

As part of the meet-and-confer in advance of this Joint Status Report, the United States informed Walmart that it intends to seek relief from the Court to permit it to access the documents that Walmart has produced into the repository of documents in *In Re National Prescription Opiate Litig.*, Case No. 1:17-md-02804-

DAP (N.D. Ohio) (the “MDL materials”), pursuant to the terms of the protective order in that case.

A. Walmart’s Position

Walmart objects to the United States’ inappropriate and premature attempt to access the MDL materials given Walmart’s pending Motion to Dismiss and the United States’ stated intention to seek leave to file an amended Complaint.

The Federal Rules of Civil Procedure are clear: “A party may not seek discovery from any source before the parties have conferred as required by Rule 26(f)” Fed. R. Civ. P. 26(d)(1) (emphasis added). Further, the scope of discovery necessarily depends on the existence and nature of any legally viable claims before the Court in Delaware. Given Walmart’s pending Motion to Dismiss and the United States’ desire to amend its Complaint, the existence of any legally viable claims—and therefore the scope of discovery—remains disputed.

Walmart therefore respectfully requests that the Court prohibit the United States from accessing the MDL materials in connection with this case until discovery has opened following the parties’ Rule 26(f) conference. Walmart requests the opportunity to provide additional argument in support of its position when the United States formally raises the issue with the Court.

B. The United States' Position

The United States disagrees with Walmart's position that accessing the MDL materials is "seek[ing] discovery" within the meaning of Fed. R. Civ. P. 26(d)(1). As made clear in case law and the history of Rule 26, the limitation on "discovery" in Rule 26(d)(1) limits the use of the various enforceable discovery devices identified in the Federal Rules of Civil Procedure, and accessing the MDL materials does not require the United States to use any of those devices or place any burden on Walmart. To gain access to the MDL materials, the United States simply needs to sign a certification in the protective order governing those materials, which are maintained by a third-party vendor. The Judicial Panel on Multidistrict Litigation recently stated that there is "no reason why the parties in subsequent actions [outside of the MDL], subject to the same conditions imposed on the parties to MDL No. 2804, should not be able to avail themselves of the documents and depositions accumulated in this MDL." *See In re Nat'l Prescription Opiate Litig.*, Case No. MSN/3:21-cv-00246, No. 39, at 2 (J.P.M.L. April 8, 2022).

Moreover, even if Rule 26(d)(1) did apply to accessing the MDL materials, it would be fair and appropriate for the Court to permit the United States to access the materials at this time. Walmart itself—along with thousands of other litigants both within and outside of the MDL—has unfettered access to the entire repository, including tens of thousands of documents produced by the United

States. Equal access by the United States to the MDL materials now that this case is unstayed would be consistent with the purpose of the repository, namely to create efficiencies in opioid-related cases without causing burden or prejudice to the parties in those cases.

The United States will follow the Court's procedures to raise this dispute and respectfully offer further argument in support of its position through those procedures.

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/s/ Robert W. Whetzel

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